

REMARKS

Claims 60-69 and 71-95 were pending. Claims 60-67, 78-81 and 89-93 are allowed. Applicant notes that claim 81 is allowed and depends from rejected claim 76; thus, Applicant requests clarification regarding the status of claim 81. Claims 69, 74, 88, 94 and 95 have been canceled without prejudice. Applicant reserves the right to pursue the subject matter of the canceled claims in one or more related applications.

Claim 68 has been amended to replace “ADP-heat shock protein 70-peptide complex” with “ADP-mammalian heat shock protein 70-antigenic molecule complexes,” wherein the antigenic molecules are selected from the group consisting of peptides and proteins. Support for these amendments may be found throughout the specification, for example, at page 10, lines 11-22; page 14, lines 27-32; page 15, line 32 to page 16, line 5; page 22, lines 8-10; page 23, line 5 to page 25, line 17; page 29, line 26 to page 35, line 22; and page 36, lines 25-32. Support for the recitation of *mammalian* heat shock protein 70 may be found throughout the specification, for example, at page 15, line 31 and page 16, lines 25-35. Claim 68 also has been amended to specify that the antigenic molecules comprise an antigenic peptide or antigenic protein displaying antigenicity of an antigen of a cancer or of an infectious agent. Support for this amendment may be found throughout the specification, for example, at page 15, lines 13-19; page 17, lines 19-21; page 22, line 15 to page 23, line 4; page 23, line 20 to page 25, line 17; page 33, lines 5-9; page 34, lines 6-10; and page 36, lines 25-32.

Claims 71-87, which depend directly or indirectly from claim 68, have been amended accordingly to be consistent with amended claim 68. The claim dependencies of claims 81-87 have been amended. Also, claims 81-87 have been amended to specify that the antigenic molecules are peptides. Support for this amendment may be found throughout the specification, for example, at page 10, lines 11-22.

Claims 60, 61 and 90 have been amended for consistency with respect to the use of a hyphen in “heat shock protein 70-peptide complexes.”

Claim 62 has been amended to recite complexes in the plural form instead of the singular form for clarity and consistency.

New claims 96-109 have been added. Support for the new claims may be found throughout the specification, for example, as set forth in the table below.

New Claim	Exemplary Support in the Specification
96	page 29, lines 16-25; and page 42, lines 24-27
97	page 34, line 32 to page 35, line 6
98	page 35, lines 7-12
99	page 35, lines 13-17
100	page 35, lines 18-22
101	page 34, lines 11-26
102	page 43, line 15 to page 44, line 5
103, 107	page 15, line 31
104, 105, 106	page 15, line 29 to page 16, line 24 (as amended herein)
108, 109	page 25, lines 1-8

Thus, no new matter is added by these amendments. Upon entry of the amendments made herein, claims 60-68, 71-87, 89-93 and 96-109 will be pending.

The specification has also been amended at page 16, line 25 to replace material incorporated by reference with actual text referred to, in accordance with 37 C.F.R. § 1.57(f) and M.P.E.P. §§ 2163.07(b) and 608.01(p). More specifically, Lindquist *et al.*, 1988, “The Heat-Shock Proteins”, *Annu. Rev. Genet.* 22:631-677 (hereinafter “Lindquist”, Reference BS of record) was incorporated by reference at page 16, lines 19-21 of the specification. The actual text of page 634, lines 4 to 21 of Lindquist, which describes hsp110, has been inserted at page 16, line 25 of the specification, except that the symbols indicating reference citations in the text of Lindquist have been replaced by the actual reference citations. Pursuant to 37 C.F.R. § 1.57(f) and M.P.E.P. § 608.01(p), the undersigned states that the material being inserted at page 16, line 25 of the specification is the material previously incorporated by reference in the specification as filed at page 16, lines 19-21, and the amendment contains no new matter.

I. The Claim Objections Should Be Withdrawn

Claims 82-88 are objected to under 37 C.F.R. § 1.75 as allegedly being a substantial duplicate of claims 68-75. Prior to the amendments made herein, claims 68-75 were directed to an “ADP-heat shock protein 70-*peptide* complex” and claims 82-88 were directed to an

“ADP-heat shock protein 70-*protein* complex.” Applicant respectfully requests withdrawal of these claim objections for the reasons set forth below.

Claim 68, as amended, is directed to ADP-mammalian heat shock protein 70-antigenic molecule complexes wherein the antigenic molecules are proteins or peptides. Claim 88 has been canceled, and claims 82-87 have been amended to depend directly or indirectly from claim 68 and to further specify that the antigenic molecules are peptides. These amendments obviate the objections to claims 82-88. Claims 82-87, as amended, further modify the claims from which they depend, and are not substantial duplicates of claims 68-75. In particular, Applicant notes that, consistent with the understanding in the art, peptides are generally construed to be short polymers of up to approximately 60 amino acid residues linked by peptide bonds, and proteins are generally construed to be polymers with approximately more than 60 amino acid residues linked by peptide bonds. See, *e.g.*, Robert H. Abeles, Perry A. Frey & William P. Jencks, *Biochemistry*, p. 42 (Jones and Bartlett Publishers, Inc. 1992), submitted herewith as Reference C01 of record.

Accordingly, the claim objections with respect to claims 82-88 are moot and should be withdrawn.

II. The Rejection under 35 U.S.C. § 112, 2nd Paragraph, Should Be Withdrawn

Claims 72 and 85 are rejected under 35 U.S.C. § 112, 2nd paragraph, as allegedly being indefinite. Specifically, the Examiner contends that it is not clear how claims 72 and 85, which recite that the complexes are derived from the same person, further modifies claims 71 and 74, respectively, which specify that the ADP-heat shock protein 70-peptide complex is made *in vitro* (see the Office Action at page 2). Applicant disagrees for the reasons set forth below.

Firstly, claim 85 has been amended to delete the recitation that the heat shock protein 70 and the protein are from the same individual, thus, obviating the rejection with respect to claim 85.

Secondly, Applicant submits that the claimed ADP-mammalian heat shock protein 70-antigenic molecule complexes made *in vitro* may comprise “a heat shock protein 70 and a peptide from the same individual.” For example, prior to complexing, mammalian heat shock protein 70 obtained from an individual may be pretreated with ATP or low pH to

remove any peptides that may be associated with the heat shock protein 70 (see the specification at page 29, lines 28-30 and page 36, lines 5-7); antigenic peptides (*i.e.*, antigenic molecules) can be eluted from, *e.g.*, heat shock protein-peptide complexes or MHC-peptide complexes obtained from the same individual (see the specification at page 30, line 1 to page 31, line 31); and the mammalian heat shock protein 70 free of associated peptides can be mixed in the presence of ADP with the eluted antigenic peptides (*i.e.*, antigenic molecules) from the same individual to form *in vitro* ADP-mammalian heat shock protein 70-antigenic molecule complexes. Thus, claim 72 properly modifies claim 71, from which it depends, by specifying that the mammalian heat shock protein 70 and the antigenic peptide or the antigenic protein of the *in vitro* complexes are from the same individual. Accordingly, the rejection under 35 U.S.C. § 112, 2nd paragraph, for indefiniteness should be withdrawn.

III. The Rejection under 35 U.S.C. § 102(b) Should Be Withdrawn

Claims 68, 69, 71, 76, 77, 82-84, 94 and 95 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Palleros *et al.*, J. Biol. Chem. May 1994, 269(18):13107-13114 (“Palleros”). The Examiner contends that Palleros teaches an isolated ADP-heat shock protein complex. Applicant submits that the rejection should be withdrawn for the reasons set forth below.

The legal test for anticipation under 35 U.S.C. § 102 requires that each and every element of the claimed invention be disclosed in a prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the public in possession of the invention. *W.L. Gore Associates v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983); *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985).

Independent claim 68, as amended, is directed to ADP-mammalian heat shock protein 70-antigenic molecule complexes in substantially purified form as indicated by apparent homogeneity upon electrophoresis in a polyacrylamide gel wherein the antigenic molecules are peptides or proteins that comprise an antigenic peptide or antigenic protein displaying antigenicity of an antigen of a cancer or of an infectious agent.

Palleros teaches a complex comprising human hsp72 from 293 cells and reduced carboxymethylated alpha-lactalbumin (RCMLA) incubated in the presence of ADP (see Palleros at page 13110, col. 1, last paragraph; Figure 7 at page 13110; and page 13107, col. 2, last paragraph). RCMLA is a permanently unfolded form of alpha-lactalbumin, which is a

protein found in milk. RCMLA is not an antigenic peptide or antigenic protein that displays antigenicity of an antigen of a cancer or of an infectious agent. Thus, Palleros fails to teach an element of the claims, *i.e.*, the presence in the complexes of an antigenic peptide or antigenic protein that displays antigenicity of a cancer or of an infectious agent. Accordingly, Palleros fails to teach the ADP-mammalian heat shock protein 70-antigenic molecule complexes specified in the claims, and does not anticipate the ADP-mammalian heat shock protein 70-antigenic molecule complexes of the claimed invention.

Thus, the rejection under 35 U.S.C. § 102(b) should be withdrawn.


CONCLUSION

It is estimated that no additional fee is due in connection with the filing of this response. However, should the Patent Office determine otherwise, please charge the fee to Jones Day Deposit Account No. 50-3013.

Applicant believes that all the claims are in condition for allowance. Withdrawal of all rejections and an allowance are earnestly sought. If there are any outstanding issues remaining, the Examiner is invited to contact the undersigned.

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Respectfully submitted,

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